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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC., Defendants.	Case No. 2:15-cv-00326-SDW-SCM **ANSWER TO AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND COUNTERCLAIMS** ***Document Electronically Filed***

Defendants Par Pharmaceutical Companies, Inc. ("Par") and Par Pharmaceutical, Inc. ("Par Pharmaceutical") (collectively "Defendants"), answer and respond to each of the allegation of Plaintiff Supernus Pharmaceuticals, Inc. ("Plaintiff") as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8, 298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), and 8,889,191 ("the '191 patent") attached hereto as Exhibits A, B, C, D, and E respectively.

Answer: Defendants admit that Plaintiff purports to bring this action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving United States Patent Nos. 8,298,576 (the "'576 patent"), 8, 298,580 (the "'580 patent"), 8,663,683 (the "'683 patent"), 8,877,248 (the "'248 patent") and 8,889,191 (the "'191 patent"). Defendants further admit that what appears to be copies of the '576 patent, the '580 patent, the '683 patent, the '248 patent, and the '191 patent are attached to the Amended Complaint as Exhibits A, B, C, D, and E, respectively. Defendants deny that Plaintiff properly states a claim for patent infringement, and deny the remaining allegations in paragraph 1 of the Amended Complaint.

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Amended Complaint and therefore deny them.

3. Upon information and belief, Par is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard., [sic] Woodcliff Lake, New Jersey 07677.

Answer: Defendants admit the allegations of paragraph 3 of the Amended Complaint.

4. Upon information and belief, Par is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; (ii) through its various subsidiaries, including defendant Par Pharmaceutical, the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval to market generic drugs throughout the United States; and (iii) through its various subsidiaries, including defendant Par Pharmaceutical, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

Answer: Defendants admit that Par Pharmaceutical is a subsidiary of Par. Defendants deny the remaining allegations in paragraph 4 of the Amended Complaint.

5. Par's Form 10-K, filed with the U.S. Securities and Exchange Commission on March 18, 2014 states that "[t]he majority of [its] generic products are distributed under an associated Abbreviated New Drug Application ('ANDA') owned or licensed by us and approved by the Food and Drug Administration," and that "[a]s of the fourth quarter of 2013, we or our strategic partners had approximately 73 ANDAs pending with the FDA." Par Pharmaceutical Companies, Inc.'s Form 10-K for the Year Ended December 31, 2013 ("Form 10-K") at 4. Par's Form 10-K further states that it "operate[s] primarily in the United States, the largest generics market in the world, where [it] ranked fifth in revenues among all generic drug companies," and that it markets its "generic products primarily to wholesalers, drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, and government." *Id.* at 4-5.

Answer: Defendants admit that on or about March 18, 2014, Par filed a Form 10-K with the U.S. Securities and Exchange Commission. Defendants refer to the Form 10-K with respect to its contents. Defendants deny the remaining allegations of paragraph 5 of the Amended Complaint.

6. According to Par's Form 10-K, Par conducts its business of "developing, licensing, manufacturing, marketing and distributing," *inter alia*, generic pharmaceutical products "principally through its wholly owned operating subsidiary, Par Pharmaceutical, Inc." Form 10-K at 3. Par's Form 10-K further identifies "Par Pharmaceutical" as its generic products division. *Id.* at 3, 42. Par's Form 10-Q, filed with the U.S. Securities and Exchange Commission on November 12, 2014, reports over $871 million in revenues for the Par Pharmaceutical business segment in the nine months ended September 30, 2014. Par Pharmaceutical Companies, Inc.'s Form 10-Q for the Quarterly Period Ended September 30, 2014 at 39.

Answer: Defendants admit that on or about November 12, 2014, Par filed a Form 10-Q with the U.S. Securities and Exchange Commission. Defendants refer to the Form 10-Q with respect to its contents. Defendants deny the remaining allegations of paragraph 6 of the Amended Complaint.

7. Upon information and belief, Par Pharmaceutical is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Upon information and belief, Par Pharmaceutical is registered as a drug manufacturer and wholesale distributor in the State of New Jersey under the registration number 5004032.

Answer: Defendants aver Par Pharmaceutical is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Defendants further aver Par Pharmaceutical is registered as a drug manufacturer and wholesale distributor in the State of New Jersey under the registration number 5004032. Defendants deny the remaining allegations of paragraph 7 of the Amended Complaint.

8. Upon information and belief, Par Pharmaceutical is wholly owned by defendant Par. Upon information and belief, Par Pharmaceutical acts at the direction of, under the control of, and for the benefit of Par, and is controlled and/or dominated by Par. Upon information and belief, Par Pharmaceutical and Par have at least one officer and/or director in common.

Answer: Defendants admit that Par Pharmaceutical is a wholly-owned subsidiary of Par. Par further admits that Par Pharmaceutical and Par have at least one officer and/or director in common. Defendants deny the remaining allegations in paragraph 8 of the Amended Complaint.

9. Upon information and belief, Par Pharmaceutical is in the business of (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; (ii) the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

Answer: Defendants admit that Par Pharmaceutical is in the business of, *inter alia*, development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States; and the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey. Defendants deny the remaining allegations in paragraph 9 of the Amended Complaint.

10. Upon information and belief, Par Pharmaceutical prepared and then submitted and filed ANDA No. 205976 ("the Par ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Topiramate Extended Release Capsules, 25 mg, 50 mg, 100 mg, and 200 mg ("the Par Products").

Answer: Defendants aver that Par Pharmaceutical submitted ANDA No. 205976 ("the Par ANDA") to the FDA seeking FDA approval to manufacture, use, sell, offer for sale, and/or import into the United States Topiramate Extended Release Capsules having the strengths 25mg, 50mg, 100mg, and 200mg ("the Par Products"). Defendants deny the remaining allegations in paragraph 10 of the Amended Complaint.

11. Upon information and belief, Par manufactures generic pharmaceutical products for which Par Pharmaceutical is the named ANDA applicant, including Amlodipine and Valsartan Tablets (5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg, and 10 mg/320 mg); Glipizide Extended-Release Tablets (5 mg and 10 mg); and Clonazepam Orally Disintegrating Tablets, USP CIV (0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 2 mg). Upon information and belief, Defendants derive substantial revenue from the sale of such generic pharmaceutical products.

Answer: Defendants aver that Par Pharmaceutical manufactures and/or has manufactured and sells Amlodipine and Valsartan Tablets (5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg, and 10 mg/320 mg); Glipizide Extended-Release Tablets (5 mg and 10 mg); and Clonazepam Orally Disintegrating Tablets, USP CIV (0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 2 mg). Defendants deny the remaining allegations contained in paragraph 11 of the Amended Complaint.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Answer: Defendants aver that they do not contest subject matter jurisdiction for the purposes of this action.

13. This Court has personal jurisdiction over Par because, *inter alia*: (i) Par's principal place of business is located in the State of New Jersey; (ii) Par, together with its subsidiary Par Pharmaceutical, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Par regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (iv) Par is doing business in New Jersey and maintains continuous and systemic contacts with this judicial district; and (v) Par has availed itself of the rights, benefits, and privileges of this Court by asserting claims in at least four prior New Jersey actions (*Depomed, Inc. v. Impax Labs., Inc., et al.,* Civil Action No. 12-2154; *Sanofi-Aventis U.S. LLC., et al. v. Mustafa Nevsat Ilac Sanayii A.S., et al.*, Civil Action No. 08-0263; *Novartis Corp., et al. v. Par Pharm. Cos., Inc., et al.,* Civil Action No. 06-4788; *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc., et al.*, Civil Action No. 06-3533).

Answer: Defendants admit that Par's principal place of business is located in the State of New Jersey. Defendants further aver Par does not contest this Court's personal jurisdiction for the purposes of this action.

14. This Court has personal jurisdiction over Par Pharmaceutical because, *inter alia*: (i) Par Pharmaceutical is a corporation organized and existing under the laws of the State of New Jersey; (ii) Par Pharmaceutical is wholly owned by defendant Par, which has a principal place of business located in the State of New Jersey; (iii) Par Pharmaceutical, together with Par, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iv) Par Pharmaceutical regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (v) Par Pharmaceutical is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; and (vi) Par Pharmaceutical has availed itself of the rights, benefits, and privileges of this Court by asserting claims in at least eight prior New Jersey actions (*Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc.*, Civil Action No. 13-4000; *Par Pharm., Inc. v. Endo Pharm., Inc.*, Civil Action No. 05-1758; *Depomed, Inc. v. Impax Labs., Inc., et al.*, Civil Action No. 12-2154; *Sanofi-Aventis U.S. LLC., et al. v. Mustafa Nevsat Ilac Sanayii A.S., et al.*, Civil Action No. 08-0263; *Novartis Corp., et al. v. Par Pharm. Cos. Inc., et al.*, Civil Action No. 06-4788; *Ortho- McNeil Pharm., Inc. v. Kali Labs., Inc., et al.*, Civil Action No. 06-3533; *Jazz Pharm., Inc. v. Par Pharm., Inc.*, Civil Action No. 14-5139; *Purdue Pharm. Prods. L.P., et al. v. Par Pharm., Inc.*, Civil Action No. 12-6738).

Answer: Defendants admit that Par Pharmaceutical is wholly owned by defendant Par, which has a principal place of business is located in the State of New Jersey. Defendants further aver Par Pharmaceutical does not contest this Court's personal jurisdiction for the purposes of this action.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

Answer: Defendants aver that they do not contest venue in this Court for the purposes of this action.

FACTS AS TO ALL COUNTS

16. Supernus owns New Drug Application ("NDA") No. 201635, which was approved by the FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg, which Supernus markets under the name Trokendi XR®.

Answer: Defendants aver that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for New Drug Application ("NDA") No. 201635 lists "Supernus Pharms" as the applicant. Defendants further aver that the Orange Book entry for NDA No. 201635 lists the proprietary name as "Trokendi XR." Defendants further aver that the Orange Book entry for NDA No. 201635 lists the dosage as "capsule, extended release" and lists strengths 25 mg, 50 mg, 100 mg, and 200 mg. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 16 of the Amended Complaint.

17. Trokendi XR® is an antiepileptic drug indicated for: (i) initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures; (ii) adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures; and (iii) adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome.

Answer: Defendants aver that the prescribing information for Trokendi XR® currently states that Trokendi XR® is indicated for (i) "initial monotherapy in patients 10 years of age and

older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures" and (ii) "adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome." Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 17 of the Amended Complaint.

18. The '576 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

Answer: Defendants admit that, on its face, the '576 patent is entitled "Sustained-Release Formulations of Topiramate," and states that it was issued on October 30, 2012. Defendants further aver that the United States Patent and Trademark Office ("USPTO") assignment database lists "U.S. Bank National Association" as the assignee, and "Supernus Pharmaceuticals, Inc." as the assignor, of the '576 patent. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 18 of the Amended Complaint.

19. The '580 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

Answer: Defendants admit that, on its face, the '580 patent is entitled "Sustained-Release Formulations of Topiramate," and states that it was issued on October 30, 2012. Defendants further aver that the USPTO assignment database lists "U.S. Bank National Association" as the assignee, and "Supernus Pharmaceuticals, Inc." as the assignor, of the '580 patent. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 19 of the Amended Complaint.

20. The '683 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua

Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

Answer: Defendants admit that, on its face, the '683 patent is entitled "Sustained-Release Formulations of Topiramate," and states that it was issued on March 4, 2014. Defendants further aver that the USPTO assignment database lists "U.S. Bank National Association" as the assignee, and "Supernus Pharmaceuticals, Inc." as the assignor, of the '683 patent. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 20 of the Amended Complaint.

21. The '248 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

Answer: Defendants admit that, on its face, the '248 patent is entitled "Sustained-Release Formulations of Topiramate," and states that it was issued on November 4, 2014. Defendants further admit that, on its face, the '248 patent states that "Supernus Pharmaceuticals, Inc." is the assignee and Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira are the inventors. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 21 of the Amended Complaint.

22. The '191 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

Answer: Defendants admit that, on its face, the '191 patent is entitled "Sustained-Release Formulations of Topiramate," and states that it was issued on November 18, 2014. Defendants further aver that the USPTO assignment database lists "U.S. Bank National Association" as the assignee, and "Supernus Pharmaceuticals, Inc." as the assignor, of the '191 patent. Defendants

deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 22 of the Amended Complaint.

23. Pursuant to 21 U.S.C. § 355(b)(1), the '576, '580, '683,'248, and '191 patents are listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Trokendi XR®. Supernus submitted the '576, '580, '683, '248, and '191 patents to the FDA to be listed in the *Orange Book* for NDA No. 201635.

Answer: Defendants admit that the '576, '580, '683, '248, and '191 patents are listed in the *Orange Book* as covering Trokendi XR®. Defendants further admit that Supernus caused the '576, '580, '683, '248, and '191 patents to be listed in the Orange Book relative to Trokendi XR® by filing a declaration with the FDA, and that the FDA published the '576, '580, '683, '248, and '191 patent information in the Orange Book as a ministerial act. Defendants deny knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 23 of the Amended Complaint.

24. Upon information and belief, Defendants worked in concert to prepare, and then submit and file the Par ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products and included a "paragraph IV" certification seeking approval before the expiration of the '576, '580, '683, '248, and '191 patents.

Answer: Defendants admit that Par Pharmaceuticals prepared, then submitted and filed the Par ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of the Par Products, and included a "paragraph IV" certification seeking approval before the expiration of the '576, '580, '683, '248, and '191 patents. Defendants deny the remaining allegations in paragraph 24 of the Amended Complaint.

25. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R.

§ 314.95(c)(6) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)- (ii).

Answer: Defendants aver that the text of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6) speak for themselves. Defendants deny the remaining allegations in paragraph 25 of the Amended Complaint.

26. Supernus received a letter dated December 5, 2014, which was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, regarding the Par Products and the '576, '580, '683, and '248 patents (the "December 5 Notice Letter").

Answer: Defendants admit that Defendants sent Supernus a letter dated December 5, 2014 pursuant to § 505(j)(2)(B)(ii) of the FDCA, regarding the Par Products and the '576, '580, '683, and '248 patents (the "December 5 Notice Letter").

27. The December 5 Notice Letter was signed by Michelle Bonomi-Huvala, Senior Vice President, Corporate Regulatory Affairs, Par Pharmaceutical, Inc.

Answer: Defendants admit the allegations in paragraph 27 of the Amended Complaint.

28. Supernus received a letter dated January 28, 2015, which was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, regarding the Par Products and the '191 patent (the "January 28 Notice Letter").

Answer: Defendants admit that Defendants sent Supernus a letter dated January 28, 2015, pursuant to § 505(j)(2)(B)(ii) of the FDCA, regarding the Par Products and the '191 patent (the "January 28 Notice Letter").

29. The January 28 Notice Letter was signed by Michelle Bonomi-Huvala, Senior Vice President, Corporate Regulatory Affairs, Par Pharmaceutical, Inc.

Answer: Defendants admit the allegations in paragraph 29 of the Amended Complaint.

FIRST COUNT
(Defendants' Alleged Infringement of the '576 Patent)

30. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-29 of the Amended Complaint as if fully set forth herein.

31. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products.

Answer: Defendants admit that Par Pharmaceutical seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products. Defendants deny the remaining allegations in paragraph 31 of the Amended Complaint.

32. Upon information and belief, Defendants included in ANDA No. 205976 a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '576 patent.

Answer: Defendants admit that Par Pharmaceutical included in ANDA No. 205976 a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '576 patent. Defendants deny the remaining allegations in paragraph 32 of the Amended Complaint.

33. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval.

Answer: Defendants admit that Par Pharmaceutical intends to commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval. Defendants deny the remaining allegations in paragraph 33 of the Amended Complaint.

34. The submission and filing of ANDA No. 205976 with a paragraph IV certification to the '576 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products before the expiration of the '576 patent is an act of infringement by Defendants of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Defendants aver that ANDA No. 205976 requests marketing approval of the Par Products prior to the expiration of the '576 patent. Defendants deny the remaining allegations in paragraph 34 of the Amended Complaint.

35. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products that are the subject of ANDA No. 205976 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '576 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 35 of the Amended Complaint.

36. Upon information and belief, the sale or offer for sale of the Par Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 36 of the Amended Complaint.

37. Upon information and belief, Par is jointly and severally liable for Par Pharmaceutical's infringement of one or more claims of the '576 patent.

Answer: Defendants deny the allegations in paragraph 37 of the Amended Complaint.

38. Upon information and belief, Par knowingly induced Par Pharmaceutical to infringe and/or contributed to Par Pharmaceutical's infringement of one or more claims of the '576 patent.

Answer: Defendants deny the allegations in paragraph 38 of the Amended Complaint.

39. Upon information and belief, Par actively induced, encouraged, aided, or abetted Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification to the '576 patent.

Answer: Defendants deny the allegations in paragraph 39 of the Amended Complaint.

40. Par's inducement, encouragement, aiding, or abetting of Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification constitutes infringement of the '576 patent under 35 U.S.C. § 271(e)(2)(A). Further, Par's commercial use, sale, offer for sale, and/or importation of the Par Products would induce and/or contribute to Par Pharmaceutical's infringement of the '576 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. §271(c)

Answer: Defendants deny the allegations in paragraph 40 of the Amended Complaint.

41. Upon information and belief, Par's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Par Products by Par Pharmaceutical

would induce and/or contribute to third party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 41 of the Amended Complaint.

42. Upon information and belief, Par has, continues to, and will actively induce, encourage, aid, or abet Par Pharmaceutical's infringement of the '576 patent with knowledge of infringement in contravention of the rights of Supernus.

Answer: Defendants deny the allegations in paragraph 42 of the Amended Complaint.

43. Defendants' infringement of the '576 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '576 patent.

Answer: Defendants deny the allegations in paragraph 43 of the Amended Complaint.

44. As of the date of the December 5 Notice Letter, Defendants were aware of the existence of the '576 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer: Defendants admit that as of the date of the December 5 Notice Letter, Par Pharmaceutical was aware of the existence of the '576 patent. Defendants deny the remaining allegations in paragraph 44 of the Amended Complaint.

SECOND COUNT
(Defendants' Alleged Infringement of the '580 Patent)

45. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-44 of the Amended Complaint as if fully set forth herein.

46. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products.

Answer: Defendants admit that Par Pharmaceutical seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products. Defendants deny the remaining allegations in paragraph 46 of the Amended Complaint.

47. Upon information and belief, Defendants included in ANDA No. 205976 a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '580 patent.

Answer: Defendants admit that Par Pharmaceutical included in ANDA No. 205976 a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '580 patent. Defendants deny the remaining allegations in paragraph 47 of the Amended Complaint.

48. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval.

Answer: Defendants admit that Par Pharmaceutical intends to commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval. Defendants deny the remaining allegations in paragraph 48 of the Amended Complaint.

49. The submission and filing of ANDA No. 205976 with a paragraph IV certification to the '580 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products before the expiration of the '580 patent is an act of infringement by Defendants of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Defendants aver that ANDA No. 205976 requests marketing approval of the Par Products prior to the expiration of the '580 patent. Defendants deny the remaining allegations in paragraph 49 of the Amended Complaint.

50. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products that are the subject of ANDA No. 205976 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '580 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 50 of the Amended Complaint.

51. Upon information and belief, the sale or offer for sale of the Par Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 51 of the Amended Complaint.

52. Upon information and belief, Par is jointly and severally liable for Par Pharmaceutical's infringement of one or more claims of the '580 patent.

Answer: Defendants deny the allegations in paragraph 52 of the Amended Complaint.

53. Upon information and belief, Par knowingly induced Par Pharmaceutical to infringe and/or contributed to Par Pharmaceutical's infringement of one or more claims of the '580 patent.

Answer: Defendants deny the allegations in paragraph 53 of the Amended Complaint.

54. Upon information and belief, Par actively induced, encouraged, aided, or abetted Par Pharmaceutical's preparation, submission and filing of ANDA No. 205976 with a paragraph IV certification to the '580 patent.

Answer: Defendants deny the allegations in paragraph 54 of the Amended Complaint.

55. Par's inducement, encouragement, aiding, or abetting of Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification constitutes infringement of the '580 patent under 35 U.S.C. §271(e)(2)(A). Further, Par's commercial use, sale, offer for sale, and/or importation of the Par Products would induce and/or contribute to Par Pharmaceutical's infringement of the '580 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 55 of the Amended Complaint.

56. Upon information and belief, Par's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Par Products by Par Pharmaceutical would induce and/or contribute to third party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 56 of the Amended Complaint.

57. Upon information and belief, Par has, continues to, and will actively induce, encourage, aid, or abet Par Pharmaceutical's infringement of the '580 patent with knowledge of infringement in contravention of the rights of Supernus.

Answer: Defendants deny the allegations in paragraph 57 of the Amended Complaint.

58. Defendants' infringement of the '580 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus

preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '580 patent.

Answer: Defendants deny the allegations in paragraph 58 of the Amended Complaint.

59. As of the date of the December 5 Notice Letter, Defendants were aware of the existence of the '580 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer: Defendants admit that as of the date of the December 5 Notice Letter, Par Pharmaceutical was aware of the existence of the '580 patent. Defendants deny the remaining allegations in paragraph 59 of the Amended Complaint.

THIRD COUNT
(Defendants' Alleged Infringement of the '683 Patent)

60. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-59 of the Amended Complaint as if fully set forth herein.

61. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products.

Answer: Defendants admit that Par Pharmaceutical seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products. Defendants deny the remaining allegations in paragraph 61 of the Amended Complaint.

62. Upon information and belief, Defendants included in ANDA No. 205976 a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '683 patent.

Answer: Defendants admit that Par Pharmaceutical included in ANDA No. 205976 a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration

of the '683 patent. Defendants deny the remaining allegations in paragraph 62 of the Amended Complaint.

63. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval.

Answer: Defendants admit that Par Pharmaceutical intends to commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval. Defendants deny the remaining allegations in paragraph 63 of the Amended Complaint.

64. The submission and filing of ANDA No. 205976 with a paragraph IV certification to the '683 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products before the expiration of the '683 patent is an act of infringement by Defendants of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Defendants aver that ANDA No. 205976 requests marketing approval of the Par Products prior to the expiration of the '683 patent. Defendants deny the remaining allegations in paragraph 64 of the Amended Complaint.

65. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products that are the subject of ANDA No. 205976 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '683 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 65 of the Amended Complaint.

66. Upon information and belief, the sale or offer for sale of the Par Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 66 of the Amended Complaint.

67. Upon information and belief, Par is jointly and severally liable for Par Pharmaceutical's infringement of one or more claims of the '683 patent.

Answer: Defendants deny the allegations in paragraph 67 of the Amended Complaint.

68. Upon information and belief, Par knowingly induced Par Pharmaceutical to infringe and/or contributed to Par Pharmaceutical's infringement of one or more claims of the '683 patent.

Answer: Defendants deny the allegations in paragraph 68 of the Amended Complaint.

69. Upon information and belief, Par actively induced, encouraged, aided, or abetted Par Pharmaceutical's preparation, submission and filing of ANDA No. 205976 with a paragraph IV certification to the '683 patent.

Answer: Defendants deny the allegations in paragraph 69 of the Amended Complaint.

70. Par's inducement, encouragement, aiding, or abetting of Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification constitutes infringement of the '683 patent under 35 U.S.C. § 271(e)(2)(A). Further, Par's commercial use, sale, offer for sale, and/or importation of the Par Products would induce and/or contribute to Par Pharmaceutical's infringement of the '683 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 70 of the Amended Complaint.

71. Upon information and belief, Par's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Par Products by Par Pharmaceutical would induce and/or contribute to third party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 71 of the Amended Complaint.

72. Upon information and belief, Par has, continues to, and will actively induce, encourage, aid, or abet Par Pharmaceutical's infringement of the '683 patent with knowledge of infringement in contravention of the rights of Supernus.

Answer: Defendants deny the allegations in paragraph 72 of the Amended Complaint.

73. Defendants' infringement of the '683 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '683 patent.

Answer: Defendants deny the allegations in paragraph 73 of the Amended Complaint.

74. As of the date of the December 5 Notice Letter, Defendants were aware of the existence of the '683 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer: Defendants admit that as of the date of the December 5 Notice Letter, Par Pharmaceutical was aware of the existence of the '683 patent. Defendants deny the remaining allegations in paragraph 74 of the Amended Complaint.

FOURTH COUNT
(Defendants' Alleged Infringement of the '248 Patent)

75. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-74 of the Amended Complaint as if fully set forth herein.

76. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products.

Answer: Defendants admit that Par Pharmaceutical seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products. Defendants deny the remaining allegations in paragraph 76 of the Amended Complaint.

77. Upon information and belief, Defendants included in ANDA No. 205976 a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '248 patent.

Answer: Defendants admit that Par Pharmaceutical included in ANDA No. 205976 a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '248 patent. Defendants deny the remaining allegations in paragraph 77 of the Amended Complaint.

78. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval.

Answer: Defendants admit that Par Pharmaceutical intends to commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of,

FDA approval. Defendants deny the remaining allegations in paragraph 78 of the Amended Complaint.

79. The submission and filing of ANDA No. 205976 with a paragraph IV certification to the '248 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products before the expiration of the '248 patent is an act of infringement by Defendants of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Defendants aver that ANDA No. 205976 requests marketing approval of the Par Products prior to the expiration of the '248 patent. Defendants deny the remaining allegations in paragraph 79 of the Amended Complaint.

80. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products that are the subject of ANDA No. 205976 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '248 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 80 of the Amended Complaint.

81. Upon information and belief, the sale or offer for sale of the Par Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 81 of the Amended Complaint.

82. Upon information and belief, Par is jointly and severally liable for Par Pharmaceutical's infringement of one or more claims of the '248 patent.

Answer: Defendants deny the allegations in paragraph 82 of the Amended Complaint.

83. Upon information and belief, Par knowingly induced Par Pharmaceutical to infringe and/or contributed to Par Pharmaceutical's infringement of one or more claims of the '248 patent.

Answer: Defendants deny the allegations in paragraph 83 of the Amended Complaint.

84. Upon information and belief, Par actively induced, encouraged, aided, or abetted Par Pharmaceutical's preparation, submission and filing of ANDA No. 205976 with a paragraph IV certification to the '248 patent.

Answer: Defendants deny the allegations in paragraph 84 of the Amended Complaint.

85. Par's inducement, encouragement, aiding, or abetting of Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification constitutes infringement of the '248 patent under 35 U.S.C. § 271(e)(2)(A). Further, Par's commercial use, sale, offer for sale, and/or importation of the Par Products would induce and/or contribute to Par Pharmaceutical's infringement of the '248 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 85 of the Amended Complaint.

86. Upon information and belief, Par's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Par Products by Par Pharmaceutical would induce and/or contribute to third party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 86 of the Amended Complaint.

87. Upon information and belief, Par has, continues to, and will actively induce, encourage, aid, or abet Par Pharmaceutical's infringement of the '248 patent with knowledge of infringement in contravention of the rights of Supernus.

Answer: Defendants deny the allegations in paragraph 87 of the Amended Complaint.

88. Defendants' infringement of the '248 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '248 patent.

Answer: Defendants deny the allegations in paragraph 88 of the Amended Complaint.

89. As of the date of the December 5 Notice Letter, Defendants were aware of the existence of the '248 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer: Defendants admit that as of the date of the December 5 Notice Letter, Par Pharmaceutical was aware of the existence of the '248 patent. Defendants deny the remaining allegations in paragraph 89 of the Amended Complaint.

FIFTH COUNT
(Defendants' Alleged Infringement of the '191 Patent)

90. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-89 of the Amended Complaint as if fully set forth herein.

91. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products.

Answer: Defendants admit that Par Pharmaceutical seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Par Products. Defendants deny the remaining allegations in paragraph 91 of the Amended Complaint.

92. Upon information and belief, Defendants included in ANDA No. 205976 a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '191 patent.

Answer: Defendants admit that Par Pharmaceutical included in ANDA No. 205976 a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Par Products before the expiration of the '191 patent. Defendants deny the remaining allegations in paragraph 92 of the Amended Complaint.

93. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval.

Answer: Defendants admit that Par Pharmaceutical intends to commercially manufacture, use, sell, offer for sale, and/or import the Par Products upon, or in anticipation of, FDA approval. Defendants deny the remaining allegations in paragraph 93 of the Amended Complaint.

94. The submission and filing of ANDA No. 205976 with a paragraph IV certification to the '191 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products before the expiration of the '191 patent is an act of infringement by Defendants of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Defendants aver that ANDA No. 205976 requests marketing approval of the Par Products prior to the expiration of the '191 patent. Defendants deny the remaining allegations in paragraph 94 of the Amended Complaint.

95. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Products that are the subject of ANDA No. 205976 will infringe indirectly (including by inducement and/or contributory infringement) one or more claims of the '191 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 95 of the Amended Complaint.

96. Upon information and belief, the sale or offer for sale of the Par Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 96 of the Amended Complaint.

97. Upon information and belief, Par is jointly and severally liable for Par Pharmaceutical's infringement of one or more claims of the '191 patent.

Answer: Defendants deny the allegations in paragraph 97 of the Amended Complaint.

98. Upon information and belief, Par knowingly induced Par Pharmaceutical to infringe and/or contributed to Par Pharmaceutical's infringement of one or more claims of the '191 patent.

Answer: Defendants deny the allegations in paragraph 98 of the Amended Complaint.

99. Upon information and belief, Par actively induced, encouraged, aided, or abetted Par Pharmaceutical's preparation, submission and filing of ANDA No. 205976 with a paragraph IV certification to the '191 patent.

Answer: Defendants deny the allegations in paragraph 99 of the Amended Complaint.

100. Par's inducement, encouragement, aiding, or abetting of Par Pharmaceutical's preparation, submission, and filing of ANDA No. 205976 with a paragraph IV certification constitutes infringement of the '191 patent under 35 U.S.C. § 271(e)(2)(A). Further, Par's commercial use, sale, offer for sale, and/or importation of the Par Products would induce and/or contribute to Par Pharmaceutical's infringement of the '191 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer: Defendants deny the allegations in paragraph 100 of the Amended Complaint.

101. Upon information and belief, Par's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Par Products by Par Pharmaceutical

would induce and/or contribute to third party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

Answer: Defendants deny the allegations in paragraph 101 of the Amended Complaint.

102. Upon information and belief, Par has, continues to, and will actively induce, encourage, aid, or abet Par Pharmaceutical's infringement of the '191 patent with knowledge of infringement in contravention of the rights of Supernus.

Answer: Defendants deny the allegations in paragraph 102 of the Amended Complaint.

103. Defendants' infringement of the '191 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '191 patent.

Answer: Defendants deny the allegations in paragraph 103 of the Amended Complaint.

104. As of the date of the January 28 Notice Letter, Defendants were aware of the existence of the '191 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer: Defendants admit that as of the date of the January 28 Notice Letter, Par Pharmaceutical was aware of the existence of the '191 patent. Defendants deny the remaining allegations in paragraph 104 of the Amended Complaint

PRAYER FOR RELIEF

Defendants deny that Supernus is entitled to any of the relief it seeks in its Amended Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any averments of the Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiff, Defendants aver and assert the following Separate Defenses to the Amended Complaint:

1. The claims of the '576, '580, '683, '248, and '191 patents are invalid and/or unenforceable under 35 U.S.C. § 1 *et seq.* (including *inter alia*, §§ 102, 103, and/or 112) and/or the doctrine of obviousness-type double patenting.

2. Par Pharmaceutical, Inc.'s filing of ANDA No. 205976 was not an act of infringement of any claim of the '576, '580, '683,'248, and '191 patents.

3. The manufacture, use, offer for sale, sale, marketing, distributing, or importation of the Par Products would not infringe any claim of the '576, '580, '683,'248, and '191 patents.

4. Defendants do not induce or contribute to the infringement of any claim of the '576, '580, '683,'248, and '191 patents.

5. The Amended Complaint fails to state a claim for which relief may be granted.

6. The relief requested in the Amended Complaint is barred by the doctrine of estoppel and/or waiver.

COUNTERCLAIMS

Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Counterclaim Plaintiffs") assert the following Counterclaims against Supernus Pharmaceuticals, Inc. ("Counterclaim Defendant" or "Supernus"):

NATURE OF THE ACTION

1. Counterclaim Plaintiffs seek a declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §

2201 *et seq.*, that U.S. Patent Nos. 8,298,576 (the "'576 patent"); 8,298,580 (the "'580 patent"); 8,663,683 (the "'683 patent"); 8,877,248 (the "'248 patent"), and 8,889,191 ("the '191 patent") (collectively, the "Patents-in Suit") are invalid, unenforceable, and/or not infringed.

THE PARTIES

2. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

3. Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

4. Upon information and belief, Supernus is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

JURISDICTION AND VENUE

5. This Court has original and supplemental jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 1357, 1367, 2201, and 2202.

6. This Court has personal jurisdiction over Supernus based, *inter alia*, on the filing by Supernus of this lawsuit in this jurisdiction.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c), 1400(b), and Supernus's choice of forum.

BACKGROUND

8. Each of the Patents-in-Suit is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") under Trokendi XR®.

9. Counterclaim Defendant Supernus asserts in its Amended Complaint that it is the assignee of the Patents-in-Suit.

10. Par Pharmaceutical, Inc. submitted to the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") No. 205976 requesting regulatory approval to engage in the commercial manufacture, use, or sale of Topiramate Extended Release Capsules having the strengths 25mg, 50mg, 100mg, and 200mg ("the Par Products") before the expiration of the Patents-in-Suit.

11. Par Pharmaceutical, Inc. made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the Patents-in-Suit are each invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's ANDA Product.

COUNT ONE
(Declaratory Judgment Regarding U.S. Patent No. 8,298,576)

12. Counterclaim Plaintiffs re-allege paragraphs 1-11 of the Counterclaims as if fully set forth herein.

13. The claims of the '576 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

14. Par's filing of ANDA No. 205976 did not infringe any claim of the '576 patent.

15. The commercial manufacture, use, offer for sale, sale, or importation of the Par Products would not infringe any claim of the '576 patent.

16. There is an actual, substantial and continuing justiciable controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the

issuance of a declaratory judgment regarding the invalidity, unenforceability, and/or infringement with respect to the '576 patent.

17. This is an exceptional case, and Counterclaim Plaintiffs are entitled to their costs and reasonable attorneys' fees.

COUNT TWO
(Declaratory Judgment Regarding U.S. Patent No. 8,298,580)

18. Counterclaim Plaintiffs re-allege paragraphs 1-17 of the Counterclaims as if fully set forth herein.

19. The claims of the '580 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

20. Par's filing of ANDA No. 205976 did not infringe any claim of the '580 patent.

21. The commercial manufacture, use, offer for sale, sale, or importation of the Par Products would not infringe any claim of the '580 patent.

22. There is an actual, substantial and continuing justiciable controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and/or infringement with respect to the '580 patent.

23. This is an exceptional case, and Counterclaim Plaintiffs are entitled to their costs and reasonable attorneys' fees.

COUNT THREE
(Declaratory Judgment Regarding U.S. Patent No. 8,663,683)

24. Counterclaim Plaintiffs re-allege paragraphs 1-23 of the Counterclaims as if fully set forth herein.

25. The claims of the ’683 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

26. Par’s filing of ANDA No. 205976 did not infringe any claim of the ’683 patent.

27. The commercial manufacture, use, offer for sale, sale, or importation of the Par Products would not infringe any claim of the ’683 patent.

28. There is an actual, substantial and continuing justiciable controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and/or infringement with respect to the ’683 patent.

29. This is an exceptional case, and Counterclaim Plaintiffs are entitled to their costs and reasonable attorneys’ fees.

COUNT FOUR
(Declaratory Judgment Regarding U.S. Patent No. 8,877,248)

30. Counterclaim Plaintiffs re-allege paragraphs 1-29 of the Counterclaims as if fully set forth herein.

31. The claims of the ’248 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more

of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

32. Par's filing of ANDA No. 205976 did not infringe any claim of the '248 patent.

33. The commercial manufacture, use, offer for sale, sale, or importation of the Par Products would not infringe any claim of the '248 patent.

34. There is an actual, substantial and continuing justiciable controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and/or infringement with respect to the '248 patent.

35. This is an exceptional case, and Counterclaim Plaintiffs are entitled to their costs and reasonable attorneys' fees.

COUNT FIVE
(Declaratory Judgment Regarding U.S. Patent No. 8,889,191)

36. Counterclaim Plaintiffs re-allege paragraphs 1-35 of the Counterclaims as if fully set forth herein.

37. The claims of the '191 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

38. Par's filing of ANDA No. 205976 did not infringe any claim of the '191 patent.

39. The commercial manufacture, use, offer for sale, sale, or importation of the Par Products would not infringe any claim of the '191 patent.

40. There is an actual, substantial and continuing justiciable controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and/or infringement with respect to the ’191 patent.

41. This is an exceptional case, and Counterclaim Plaintiffs are entitled to their costs and reasonable attorneys’ fees.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court enter judgment in their favor and against Plaintiff and grant the following relief:

A. Declare that the claims of the ’576 patent are invalid;

B. Declare that the manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product would not infringe any claim of the ’576 patent;

C. Declare that the claims of the ’580 patent are invalid;

D. Declare that the manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product would not infringe any claim of the ’580 patent;

E. Declare that the claims of the ’683 patent are invalid;

F. Declare that the manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product would not infringe any claim of the ’683 patent;

G. Declare that the claims of the ’248 patent are invalid;

H. Declare that the manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product would not infringe any claim of the ’248 patent;

I. Declare that the claims of the ’191 patent are invalid;

J. Declare that the manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product would not infringe any claim of the ’191 patent;

K. Award Counterclaim Plaintiffs their costs and reasonable attorneys' fees; and

L. Award Counterclaim Plaintiffs such other and further relief as the Court deems just and proper.

Respectfully submitted,

SAIBER LLC

Attorneys for Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.

Dated: March 12, 2015

By:/s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendants hereby certifies that United States Patent Nos. 8,298,576, 8, 298,580, 8,663,683, 8,877,248, and 8,889,191 are also the subject of litigation in *Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 2:14-cv-7272 (SDW)(SCM) and United States Patent Nos. 8,298,576, 8, 298,580, and 8,663,683 are also the subject of litigation in *Supernus Pharm., Inc. v. Actavis, Inc.*, C.A. No. 2:14-cv-6102 (SDW)(SCM).

Dated: March 12, 2015

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Defendant seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: March 12, 2015

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)